Int'l J. Pharm. 135 (1988). Nevertheless, Apotex brought hemihydrate into its facilities, seeding its facilities with hemihydrate. App. 129a. More-over, Apotex uses an *aqueous* coating for its tablets. *Id.* at 128a-130a. In these circumstances, Apotex cannot be practicing the prior art as described in the 1977 Ferrosan patent.

Apotex's reliance on the maxims that patent claims "must be construed the same way for infringement as for invalidity," and "that which infringes, if later, anticipates if earlier," Opp. 6, is similarly misplaced. SmithKline Beecham fully accepts this principle. Its patent claim is to hemihydrate, and it asserts infringement based on Apotex's manufacture of the hemihydrate component of its product. Hemihydrate was not recognized before the inventors of the '723 patent's discovery. In contrast, there is no question that the hemihydrate in Apotex's product is recognized and appreciated. Petitioners' position is wholly consistent with all tenets of patent law that Apotex cites.

III. APOTEX'S ATTEMPTS TO MINIMIZE THE IMPORTANT, RECURRING NATURE OF THE ISSUE PRESENTED ARE WEAK AND WRONG.

Apotex maintains that the Federal Circuit's rule of inherent anticipation will not discourage innovation because, although it invalidated SmithKline Beecham's patent claim for the hemihydrate, it did not invalidate other SmithKline Beecham patent claims involving the hemihydrate. Opp. 16.

This argument wholly misses the critical point. The decision below presents an issue of recurring importance because it adopts and expands a *rule of law* that will generally thwart settled expectations embodied in extant patents and threaten the innovation that patent laws are designed to protect. As Judge Newman stated, the Federal Circuit's expanded doctrine of inherent anticipation calls into question "the patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products" and

gives rise to "uncertainty as to existing patents, as well as the negation of searches for the beneficial components of existing materials." App. 59a. As the Petition describes, not only Judge Newman, but Professor Chisum and numerous other commenters have recognized the critical importance and potentially damaging impact of the Federal Circuit's broad, new inherent anticipation doctrine. See Pet. 21-24. No use of effective claim drafting techniques (Opp. 15-16) can forestall the resulting uncertainty's damage to embedded expectations and incentives for innovation.

Moreover, the Federal Circuit's expansion of the doctrine of inherent anticipation will allow products and processes that were unknown and undetected to spring to life as patent-defeating prior art upon their discovery at some future date. This leads to the absurd result that a subject matter becomes prior art by its mere existence, though its existence was unknown and unknowable at the time of invention. This defect in the Federal Circuit's ruling cannot be remedied by artful drafting. The result will be uncertainty with respect to existing and future patents – an uncertainty that will discourage innovation by pharmaceutical drug manufacturers and all inventors who must invest millions to develop new products. See Pet. 23.

Apotex does concede that the important issue raised by the petition is recurring, but attributes its recurrence to repeated attempts by drug companies to block generic versions of drug products based on expired patents. Opp. 17. This is a red herring designed to distract the Court's attention from the vast, damaging implications of the Federal Circuit's rule. If Apotex were marketing the product described in the Ferrosan patent, SmithKline Beecham would have no quarrel with it. And, the myriad cases and differing circumstances raising the issue of inherent anticipation illustrate that the question presented extends far beyond the realm of post-patent expiration generic drugs. Under the Federal Circuit's expanded inherent-anticipation doctrine, a patent may be

invalidated by a later discovery that the claimed subject matter existed prior to the filing of the patent application – even if it existed in an undetected, undetectable quantity and thus was not part of the store of useful human knowledge.

Finally, Apotex contends that if the Court were to grant the petition, it would also "be obliged" to consider all grounds advanced in support of affirmance. Opp. 18. This is clearly wrong. The Court's standards for certiorari review, see Sup. Ct. R. 10, do not require the Court to address issues that lack general importance. *Roberts* v. *Galen of Va., Inc.*, 525 U.S. 249, 253-54 (1999). The notion that a grant of certiorari to review a specific legal issue should be accompanied by a broad review of unrelated factual issues is inconsistent with this Court's rules and practices. This Court reviews specific legal questions, not findings of fact. Apotex has made no effort to demonstrate that the additional issues it seeks to raise satisfy Rule 10.

CONCLUSION

For the foregoing reasons and those in the petition, the petition for a writ of certiorari should be granted.

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No. 05-489

In the Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, ET AL.,
PETITIONERS

v.

APOTEX CORPORATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether a compound that is inevitably produced by the prior art is inherently anticipated by the prior art, and thus not novel under 35 U.S.C. 102.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

Petitioners GlaxoSmithKline P.L.C., SmithKline Beecham Corporation d/b/a GlaxoSmithKline Inc., SmithKline Beecham P.L.C. and Beecham Group, P.L.C. filed suit alleging that respondent Apotex, Inc., and affiliates of Apotex were infringing U.S. Patent No. 4,721,723 (the '723 patent) by preparing to sell a generic version of the anti-depressant drug Paxil. Following a bench trial, the district court entered judgment for respondents, and the court of appeals affirmed.

1. In the 1970s, a company called A/S Ferrosan obtained U.S. Patent No. 4,007,196 (the '196 patent) on a set of man-made compounds known as paroxetine and its salts. When paroxetine salt is combined with other substances, it acts as an anti-depressant. Ferrosan licensed the '196 patent to petitioners, who began producing paroxetine hydrochloride (PHC), the crystalline hydrochloride salt of paroxetine. Pet. App. 2a, 113a.

In 1985, a SmithKline chemist noticed that PHC molecules in SmithKline's laboratory had bound with water to create a different form of PHC. The resulting compound is called a hemihydrate, while the original form discovered by Ferrosan is known as an anhydrate. Petitioners later discovered that a batch of paroxetine produced at their manufacturing facility in December 1984 had been PHC hemihydrate as well. Pet. App. 2a-3a, 114a, 125a-126a.

Petitioners obtained the '723 patent on (i) PHC hemihydrate; (ii) PHC hemihydrate in substantially pure form, in a particular configuration, or in an effective anti-depressant drug; and (iii) related manufacturing and treatment methods. In 1993, petitioners began marketing PHC hemihydrate under the name Paxil. Paxil is now a leading anti-depressant drug with annual sales of $3.2 billion worldwide. The '723 patent will expire at the end of 2006. Pet. App. 2a-3a, 110a, 127a, 192a.

In 1998, respondents sought approval from the Food and Drug Administration to market PHC anhydrate as a generic version of Paxil. By that time, the '196 patent, which covers PHC anhydrate, had expired. Respondents argued that the anhydrate is bioequivalent to Paxil but does not infringe the '723 patent because that patent is limited to PHC hemihydrate. See Pet. App. 3a, 119a.

2. Petitioners sued respondents for patent infringement. Petitioners argued that respondents' manufacture of PHC anhydrate would inevitably produce trace amounts of PHC hemihydrate, and therefore infringe the '723 patent. According to petitioners, the factory where respondents plan to produce the anhydrate was "seeded" with the hemihydrate when respondents experimented on Paxil, and the process of turning PHC anhydrate into a pill would cause further conversion of the anhydrate into PHC hemihydrate. Pet. App. 129a-130a.[1]

After a bench trial, the district court held that the '723 patent is not invalid, but that respondents' generic version of Paxil would not infringe the patent and that petitioners would not be entitled to relief in any event. Pet. App. 109a-182a. The court first considered whether PHC hemihydrate was "inherent in patent 196 because anyone who followed the directions in that patent would inevitably produce hemihydrate." *Id.* at 131a. Citing scientific uncertainty and the presumption of patent validity, the court ruled that PHC hemihydrate was not inherent in PHC anhydrate because it is possible that practicing the '196 patent in a non-seeded laboratory would not have produced any PHC hemihydrate. *Id.* at 132a-133a.

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[1] "Seeding" refers to a process by which a particular (and typically more stable) crystalline form of a substance having more than one crystalline form—a "seed"—is introduced into a particular environment, such as a laboratory or manufacturing facility, and then, by a molecular process that is not well understood, interacts with another (typically less stable) form of the substance and converts it into the same form as the "seed." "Seeding" a facility with PHC hemihydrate would facilitate the conversion of PHC anhydrate into PHC hemihydrate. Pet. App. 114a-116a, 121a-124a.

Nevertheless, the court concluded that petitioners could not prevail. Although claim 1 in the '723 patent covers "crystalline paroxetine hydrochloride hemihydrate," the court construed it not to claim trace amounts of the hemihydrate. Pet. App. 132a-142a. In the alternative, the court concluded that equity does not support granting petitioners relief, in part because they bear some responsibility for the seeding effect. *Id.* at 164a-169a.

3. The court of appeals affirmed. Pet. App. 1a-55a. In its initial opinion (*id.* at 60a-108a), the court rejected the district court's claim construction, and held that claim 1 applies by its terms to any amount of PHC hemihydrate. *Id.* at 69a-70a. The court then concluded that the claim is invalid under 35 U.S.C. 102(b) because PHC hemihydrate had been publicly used in clinical trials for more than one year before petitioners applied for the patent. Pet. App. 75a-82a.

The en banc court of appeals vacated the panel's original opinion addressing the issue of public use, and remanded the matter to the panel. Pet. App. 56a-57a. Simultaneously, the panel issued a new opinion which, instead of relying on the public use exception, holds that claim 1 of the '723 patent was inherently anticipated by the prior art covered by the '196 patent. *Id.* at 1a-55a.

Under 35 U.S.C. 102(b), a patent claim is invalid if "the invention was patented or described in a printed publication in this * * * country * * * more than one year prior to the date of the application for patent in the United States." The court of appeals explained that "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." Pet. App. 18a (quoting *Schering*

Corp. v. *Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)). Further, "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the art at the time the prior art is created." *Ibid.*

Reviewing the district court's factual findings, the court of appeals concluded that manufacturing PHC anhydrate pursuant to the '196 patent "inevitably results in the production of at least trace amounts of" PHC hemihydrate. Pet. App. 19a; accord *id.* at 20a, 22a. Thus, the court concluded, "the '196 patent inherently anticipates claim 1 of the '723 patent under 35 U.S.C. § 102(b)." *Id.* at 22a.

Because "SmithKline has sued Apotex for infringement of the '723 patent in an express attempt to prevent Apotex from practicing the '196 patent upon its expiration," the court emphasized that "[i]nvalidating claim 1 of the '723 patent for inherent anticipation by the '196 patent furthers th[e] policy of allowing the public to practice expired patents." Pet. App. 22a-23a. The court stressed that its holding "merely precludes patent protection for the bare compound PHC hemihydrate," and that narrower patent claims could be valid. *Id.* at 23a.

Judge Gajarsa concurred. Pet. App. 25a-55a. In his view, claim 1 is invalid because it covers not only man-made PHC hemihydrate, but also naturally occurring PHC hemihydrate, and thus "encompasses subject matter that is unpatentable under 35 U.S.C. § 101." *Id.* at 25a.

Judge Newman dissented from the order denying rehearing en banc. Pet. App. 57a-59a. She opined that if the "existence" of a compound "is not reasonably known to persons of skill in the field, its later discovery cannot be retrospectively 'inherently anticipated.'" *Id.* at 59a.

DISCUSSION

A COMPOUND THAT IS INEVITABLY PRODUCED BY THE PRIOR ART IS INHERENTLY ANTICIPATED BY THAT ART

The patent claim at issue in this case asserts exclusive rights to PHC hemihydrate—regardless of the amount, purity, or use of that compound—even though PHC hemihydrate was inevitably produced by the practice of the prior art. The court of appeals correctly held that the patent claim is invalid because PHC hemihydrate was inherently anticipated by the prior art that inevitably produced it.

Petitioners argue (Pet. 11-13) that the court of appeals departed from decisions of this Court holding that inherent anticipation occurs only if persons skilled in the art recognized the inherent matter at the time the prior art was created (as opposed to the later time when the patent applicant made the alleged discovery). This Court has squarely rejected that contention, however, by holding that a characteristic of a pre-existing product is not patentable even if no one had previously recognized that characteristic. *General Elec. Co.* v. *Jewel Incandescent Lamp Co.*, 326 U.S. 242, 247 (1945); *Ansonia Brass & Copper Co.* v. *Electric Supply Co.*, 144 U.S. 11, 18 (1892). PHC hemihydrate is a characteristic of PHC anhydrate because the anhydrate inevitably produces the hemihydrate.

The cases relied on by petitioners are distinguishable for at least three reasons: they did not involve attempts to patent pre-existing products; they did not involve patents that would prevent the public from practicing the prior art; and it was not clear in those cases that the prior art had in fact inevitably produced the allegedly inherent result. By contrast, upholding a patent claim